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| APPLICATION NO.        | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|------------------------|---------------|----------------------|------------------------------|------------------|
| 10/698,962             | 10/30/2003    | James R. Casciani    | 009103-009740US<br>TYHC:0095 | 8826             |
| 52144                  | 7590 10/16/2  | 006                  | EXAMINER                     |                  |
| FLETCHE                | R YODER (TYCO | WINAKUR, ERIC FRANK  |                              |                  |
| P.O. BOX               |               |                      | ART UNIT                     | PAPER NUMBER     |
| HOUSTON, TX 77269-2289 |               |                      | 3768                         |                  |
|                        | •             |                      |                              | ,                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)          |  |  |  |  |
|--|---|-----------------------|--|--|--|--|
|  | 10/698,962  | CASCIANI ET AL.       |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit              |  |  |  |  |
|  | Eric F. Winakur   | 3768                  |  |  |  |  |
| The MAILING DATE of this communication app Period for Reply  | k.,   |                       |  |  |  |  |
| •  |   |                       |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                       |  |  |  |  |
| Status   |   |                       |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on 13 Ju  | 1)⊠ Responsive to communication(s) filed on <u>13 July 2006</u> .   |                       |  |  |  |  |
| ·  |   |                       |  |  |  |  |
| 3) Since this application is in condition for allowar  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                       |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |                       |  |  |  |  |
| Disposition of Claims  |   |                       |  |  |  |  |
| 4) Claim(s) <u>72-95</u> is/are pending in the application.  |   |                       |  |  |  |  |
| 4a) Of the above claim(s) 73-83 and 85-95 is/are withdrawn from consideration.   |   |                       |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |                       |  |  |  |  |
| 6)⊠ Claim(s) <u>72 and 84</u> is/are rejected.   | 6)⊠ Claim(s) <u>72 and 84</u> is/are rejected.  |                       |  |  |  |  |
| 7) Claim(s) is/are objected to.  | 7) Claim(s) is/are objected to.   |                       |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  |   |                       |  |  |  |  |
| Application Papers   |   |                       |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |                       |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>30 October 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.   |   |                       |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                       |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                       |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                       |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                       |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  |   |                       |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |                       |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |                       |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |                       |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |                       |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                       |  |  |  |  |
| Attacherouta   |   |                       |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)   |   |                       |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Da   | Paper No(s)/Mail Date |  |  |  |  |
| Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date  | 5)  | atent Application     |  |  |  |  |
| . 350(5,   |   |                       |  |  |  |  |

## **DETAILED ACTION**

#### Election/Restrictions

1. Claims 73 - 83 and 85 - 95 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 May 2005.

## Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 72 and 84 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims appear to be directed to processing data to determine physiological information, in particular, the blood oxygen saturation, rather than a practical application of the physiological information. The claim does not result in a physical transformation nor does it appear to provide a useful, concrete and tangible result. Specifically, it does not appear to produce a tangible result because emitting and detecting light necessary to measure the blood oxygen saturation is nothing more than data gathering as a precursor for mathematical processing based upon a law of nature (the steps of which are not set forth). The claim fails to use or make available for use the result of the determination to enable its functionality and usefulness to be realized. A practical application is not explicitly recited in the claims nor does it flow inherently therefrom. Therefore, claims 72 and 84 appear to be non-statutory.

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Applicant is referred to "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" published in the Official Gazette Notices of 22 November 2005 for further details on statutory subject matter. A copy is available online at <a href="http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm">http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm</a>.

## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 72 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (USPN 5,902,235 previously cited) in view of Baker et al. Lewis et al. teach an oximeter that emits and detects light at measurement wavelengths including 735 nm and at a reference wavelength at 805 nm (a known isobestic point for oximetry measurements). Thus, Lewis et al. teach all of the features of the claimed invention except that light between 880 and 940 nm is emitted and detected. Baker et al. teach 880 nm light is a suitable wavelength for performing the isobestic measurement in an oximeter arrangement (column 7, lines 61 66). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lewis et al. to measure at 880 nm instead of 805 nm, since Baker et al. teach that this is an alternate wavelength to perform an isobestic measurement in an oximeter, and it has generally been held to be within the skill level of the art to substitute alternate equivalent expedients.

#### Double Patenting

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6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 72 and 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 5,421,329 in view of Baker et al. The claim of the patent includes an oximeter emitting at 735 nm and at an infrared wavelength in a range useful for adults, but does not particularly teach the infrared wavelength range. However, Baker et al. (column 7, lines 61 - 66) teach that 880 nm was one such wavelength. Thus, it would have been obvious to implement the method of the patent with an infrared wavelength of 880 nm, since the claimed method requires an infrared wavelength useful for adults and Baker et al. teach that 880 nm was one such wavelength. One in possession of the claim of the patent as modified by Baker et al. would necessarily be in possession of the method of the instant

application, since the claims of the application are broader than those of the patent as modified.

- 8. Claims 72 and 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 5,782,237 in view of Baker et al. The claim of the patent includes an oximeter emitting at 735 nm and at an infrared wavelength in a range useful for a patient having high saturation, but does not particularly teach the infrared wavelength range. However, Baker et al. (column 7, lines 61 66) teach that 880 nm was one such wavelength. Thus, it would have been obvious to implement the method of the patent with an infrared wavelength of 880 nm, since the claimed method requires an infrared wavelength useful for patients with a high saturation and Baker et al. teach that 880 nm was one such wavelength. One in possession of the claim of the patent as modified by Baker et al. would necessarily be in possession of the method of the instant application, since the claims of the application are broader than those of the patent as modified.
- 9. Claims 72 and 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 6,272,363. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one in possession of the sensor as claimed in the patent to use it to perform measurements in its intended manner. One performing such measurements would necessarily perform the steps set forth in the claims of the instant application, since the claims of the patent are narrower than those of the application, and thus would be in possession of said steps.

- 10. Claims 72 and 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,662,033. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one in possession of the sensor as claimed in the patent to use it to perform measurements in its intended manner. One performing such measurements would necessarily perform the steps set forth in the claims of the instant application, since the claims of the patent are narrower than those of the application, and thus would be in possession of said steps.
- 11. Claims 72 and 84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of copending Application No. 11/407,725. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one in possession of the sensor as claimed in the co-pending application to use it to perform measurements in its intended manner. One performing such measurements would necessarily perform the steps set forth in the claims of the instant application, since the claims of the co-pending application are narrower than those of the instant application, and thus would be in possession of said steps.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 72 and 84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 11/407,771 in view of Baker et al. The claim of the copending

application includes an oximeter emitting at 735 nm and at an infrared wavelength in a range useful for adults, but does not particularly teach the infrared wavelength range. However, Baker et al. (column 7, lines 61 - 66) teach that 880 nm was one such wavelength. Thus, it would have been obvious to implement the method of the copending application with an infrared wavelength of 880 nm, since the claimed method requires an infrared wavelength useful for adults and Baker et al. teach that 880 nm was one such wavelength. One in possession of the claim of the copending application as modified by Baker et al. would necessarily be in possession of the method of the instant application, since the claims of the application are broader than those of the copending application as modified.

This is a <u>provisional</u> obviousness-type double patenting rejection.

#### Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 574-272-1000.

Eric F Winakur Primary Examiner Art Unit 3768